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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/574,443	05/19/2000	Bassil I. Dahiyat	A-68064-1/RFT/RMS/RMK	8666

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/574,443

Applicant(s)

DAHIYAT et al.

Examiner

Christine Saoud

Art Unit

1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 28, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 7-17, and 22-29 is/are pending in the application.
- 4a) Of the above, claim(s) 23-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 7-17, and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Claims 1, 2, and 4-6 have been canceled and claims 3, 7, 8, 10, 11 and 17 have been amended as requested in the amendment of paper #19, filed 28 March 2003. Claims 3, 7-17, and 22-29 are pending in the instant application.

Claims 23-29 remain withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. See also paper #17.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed 28 March 2003 have been fully considered but they are not deemed to be persuasive.

Claim Objections

5. Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything which would not also infringe the basic claim. In the instant case, the nucleic acid could be infringed without infringing the claim from which it depends, i.e. the protein claim. Therefore, the claim is improperly dependent and should be rewritten in independent form.

6. Claim 10 is objected to because of the following informalities: it refers to amino acid sequences of Figures without reference to the SEQ ID NO: for the sequences. In the instant case, the claims should not refer to the Figures, but rather the sequence identifiers which are associated with the sequences in the Figures. For one, the numbering of the Figures is subject to change at time of allowance and secondly, 37 CFR 1.821(d) requires the use of a Sequence identifier in the description or claims of a patent application whenever discussion of a sequence which is set forth in the Sequence Listing is made (see MPEP 2422). Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3, 7-17, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is directed to a “non-naturally occurring IA protein comprising a substitution. However, there is no structural starting point from which to make the substitutions. The term “IA protein” is not art recognized as having a particular structure, unlike the recitation of insulin, for example. The specification indicates that IA proteins are proteins not found in nature and comprise amino acid sequence that are less than about 98% identical to human insulin. Therefore, in the absence of a positive recitation of structure from which to make substitutions, the metes and bounds of what is being claimed cannot be determined. Furthermore, there is no antecedent basis for the positions “B4-Y” and “B4-F” since no structure has been associated with “IA protein”. It is suggested that the claim be directed to a protein of a specific structure (which identifies an A-chain with particular structure and a B-chain with particular structure) wherein the protein has an amino acid substitution selected from the group consisting of tyrosine at B4 and phenylalanine at B4. Again, the claim requires antecedent basis for the amino acid position “B4”.

Claims 7-8 are also directed to “non-naturally occurring IA protein[s]” comprising substitutions, wherein there is no structural starting point from which to make the substitutions. There is also no antecedent basis for the amino acid positions which are listed since there is no structure to the “IA protein”.

Claims 3, 8, and 10 recite “IA protein” which is indefinite since this term is not recognized in the art and the specification fails to provide a positive recitation of structure for this term. The claims previously used this term in conjunction that it was an insulin with amino acid substitutions, but the claims currently do not include these limitations. It is suggested that the claims do not recite “IA protein” in light of the lack of an appropriate definition such that one of ordinary skill in

the art would recognize the metes and bounds of the term. It would appear that the claims are directed to insulin molecules which have amino acid substitutions at particular amino acid positions in the A and/or B chains. The use of the term "protein" in conjunction with the starting material being the amino acid sequence of insulin and the recitation of which amino acid positions are to be substituted would convey the disclosed invention in a clear and definite manner.

Claims 9, 11-16, 17 and 22 are indefinite for depending from indefinite claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Brange et al. (U.S. Pat. No. 5,618,913) for the reasons of record in paper #17.

Brange et al. teach a number of different insulin analogues, wherein the analogues are non-naturally occurring insulin molecules which have an activity of insulin. Brange et al. further teach substitutions at positions 1, 2, 5, 9, 10, 12, 14, 16-18, 20, and 26-28 of the B-chain and positions 8-10, 13, and 21 of the A-chain (see claim 12 at column 35), meeting the limitations of claim 8.

Applicant asserts that the claimed invention requires at least 2 substitutions from the A-chain and at least 5 substitutions from the B-chain. However, Brange et al. appears to encompass these limitations, absent evidence to the contrary. Applicant additionally argues that "the specific

amino acid substitutions in the present invention are distinguishable from those made by Brange”, however, the claim does not require any specific substitution. Therefore, the rejection is being maintained. If specific amino acids were indicated to be substituted at the recited positions, this would more likely than not obviate this ground of rejection.

Conclusion

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud